Many Covid-19 Vaccines Were Studied With Saline Placebos

By Vincent Iannelli, MD / December 9, 2020 / COVID-19 vaccine, hidden ingredients, ingredients, moving the goalposts, placebos, residual ingredients, saline placebo

Remember how some folks were calling for saline placebos in vaccine clinical trials?

Table 1: Clinical Trials Submitted in Support of Efficacy and Safety Determinations of the Pfizer-BioNTech COVID-19 Vaccine

Study Number/ Country	Description	BNT162b2 (30 µg)* participants (n)	Placebo participants (n)	Study Status
C4591001 USA, Argentina, Brazil, Germany, S. Africa, Turkey	Phase 1,2,3 randomized, placebo-controlled, observer-blind, to evaluate safety, reactogenicity, and efficacy of COVID-19 vaccine.	Phase 1: 24 Phase 2/3: 21823	Phase 1: 8 Phase 2/3: 21828	Ongoing
BNT162-01 Germany	Phase 1/2 randomized, open-label, to evaluate safety and immunogenicity, dose escalation	12	0	Ongoing

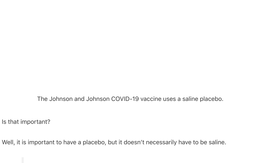
No total number of randomized participants reported with other dose levels and other mRNA vaccine candidates.
*Phase 1 studies included additional participants vaccinated with other dose levels and other mRNA vaccine candidates.
Studies C4591001 and BNT162-01 started in April 2020 (first participant, first visit).

The Pfizer-BioNTech COVID-19 vaccine uses a saline placebo.

What are they going to complain about now???

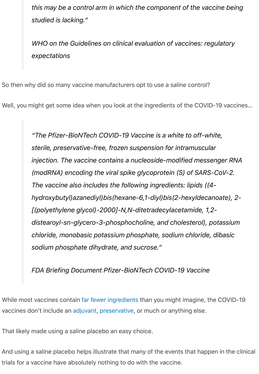
Many Covid-19 Vaccines Were Studied With Saline Placebos

No doubt they will find something, but next time you hear someone complain about placebos, you can let them know that most of the COVID-19 vaccines being developed do indeed use saline.


If volunteers enroll in this study, are they certain to receive the vaccine?
No, this is a randomized double-blind study. Randomization means that each person has an equal chance of receiving the actual Moderna mRNA vaccine or the saline injection. Half of the volunteers (50%) will receive the vaccine and half will receive a saline solution placebo. Double-blind means that neither participants nor study team members know whether participants received the vaccine or the placebo. This is done to protect the integrity of the study.

The Moderna COVID-19 uses a saline placebo.

And they use saline placebos!



The Johnson and Johnson COVID-19 vaccine uses a saline placebo.

Is that important?

Well, it is important to have a placebo, but it doesn't necessarily have to be saline.

> *"Placebo Control – A comparator in a vaccine trial that does not include the antigen under study. In studies of monovalent vaccines this may be an inert placebo (e.g. saline solution or the vehicle of the vaccine), or an antigenically different vaccine. In combined vaccines, this may be a control arm in which the component of the vaccine being studied is lacking."*
>
> *WHO on the Guidelines on clinical evaluation of vaccines: regulatory expectations*

So then why did so many vaccine manufacturers opt to use a saline control?

Well, you might get some idea when you look at the ingredients of the COVID-19 vaccines...

> *"The Pfizer-BioNTech COVID-19 Vaccine is a white to off-white, sterile, preservative-free, frozen suspension for intramuscular injection. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. The vaccine also includes the following ingredients: lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose."*
>
> *FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine*

While most vaccines contain far fewer ingredients than you might imagine, the COVID-19 vaccines don't include an adjuvant, preservative, or much or anything else.

That likely made using a saline placebo an easy choice.

And using a saline placebo helps illustrate that many of the events that happen in the clinical trials for a vaccine have absolutely nothing to do with the vaccine.

There were four deaths in these COVID-19 clinical trials in people who got an injection of saline.

Like the deaths in the folks who got saline, the two deaths in the vaccine group in these clinical trials had nothing to do with the vaccine.

> *"A total of six (2 vaccine, 4 placebo) of 43,448 enrolled participants (0.01%) died during the reporting period from April 29, 2020 (first participant, first visit) to November 14, 2020 (cutoff date). Both vaccine recipients were >55 years of age; one experienced a cardiac arrest 62 days after vaccination #2 and died 3 days later, and the other died from arteriosclerosis 3 days after vaccination #1. The placebo recipients died from myocardial infarction (n=1), hemorrhagic stroke (n=1) or unknown causes (n=2); three of the four deaths occurred in the older group (>55 years of age). All deaths represent events that occur in the general population of the age groups where they occurred, at a similar rate."*
>
> *Pfizer-BioNTech COVID-19 Vaccine FDA Briefing Documents.*

Although they might have more mild and moderate side effects than more commonly used vaccines, you can be assured that the COVID-19 vaccines that are being approved are safe and effective, and if it is important to you, know that many were studied with a saline placebo.

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